

Status of the Claims

Claims 1-9 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Claims 10-22 have been withdrawn from further consideration as being directed to nonelected inventions. Claims 23-45 are added to more clearly define the invention. Support for new claims 23-45 is found in the specification as summarized below.

Amendments to the Specification and Claims

The above amendments to page 19 of the specification, insert missing ATCC numbers into the specification and replace "anti-κ8" with "anti-λ8". Support for the missing ATCC numbers is provided by the attached ATCC Deposit Form. As shown by the attached deposit receipt, the three hybridoma cell lines were deposited on May 21, 1999, with the following ATCC numbers: PTA-103 (λ8 (31-8C7)), PTA-104 (κ1 (57-18H12)), and PTA-105 (κ4 (11-F4)). Support for replacing "anti-κ8" with "anti-λ8" is found on page 18, lines 16 and 17, where the specification refers to the antibody as λ8 (31-8C7).

The new claims, as were original claims 1-9, are directed to methods of administering an immunoglobulin polypeptide or a fragment thereof that binds to an amyloid fibril in a patient. The cancellation of claims 1-9 and the introduction of new claims 23-45 do not add prohibited new matter. Support for new claims 23-45 are summarized in Table 1.

Claims	Support in Specification
23	Page 5, line 10; Page 13, lines 25 and 26
24	Page 4, lines 20 and 21; Page 19, lines 8-27; Page 13, lines 25 and 26
25, 27	Page 4, lines 20 and 21; Page 19, lines 8-27; Page 13, lines 25 and 26
26	Page 5, line 11
28	Original claim 2
29	Original claim 3
30	Original claim 4
31	Page 15, lines 6-14

32	Original claim 5
33	Original claim 6
34	Original claim 7
35	Original claim 8
36	Original claim 9
37, 38	Page 8, lines 22 and 23
39	Page 18, lines 28 and 29
40, 41	Page 19, lines 20-27; Page 20, lines 12-14
42	Page 4, line 24 ; Page 13, line 22
43	Page 19, lines 19-27; Page 18, lines 11-21
44	Original claim 1
45	Original claim 1

Applicant respectfully submits that no prohibited new matter has been introduced by this Amendment.

**The Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 9 is rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have canceled claim 9 without prejudice and have amended the specification to insert the ATCC accession numbers for the monoclonal antibodies. The deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application. Accordingly, this rejection respectfully has become moot.

**The Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Applicants have canceled claims 1-9 and have added new claims 23-45 to more clearly claim the subject matter of the invention. Since claims 1-9 have been canceled without prejudice, this rejection respectfully has become moot.

**The Rejections Under 35 U.S.C. § 102(b)**

Claims 1, 3, and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Walker *et al.*

Claims 1, 3, 4, and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Konig *et al.*

Applicants respectfully submit that cancellation of claims 1, 3, 4, and 8 without prejudice renders these rejections moot. The claims as they stand are directed to a method of inhibiting the formation of amyloid deposits, removing amyloid deposits, or modulating the formation of amyloid deposits in a patient comprising administering to the patient an immunoglobulin polypeptide or fragment thereof that binds to an amyloid fibril or component or precursor thereof. The cited references, Walker *et al.* and Konig *et al.*, disclose the use of monoclonal antibodies as tools for labeling amyloid deposits in diagnostic assays. Applicants respectfully submit that neither of these cited references disclose a method of administering an antibody formulated to inhibit the formation of amyloid deposits, remove amyloid deposits, or modulate the formation of amyloid deposits in a patient. Accordingly, Applicants request withdrawal of these two rejections under 35 U.S.C. § 102(b).

**The Rejection of Under 35 U.S.C. § 103(a)**

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wrightham *et al.*, Walker *et al.*, Konig *et al.*, and Applicants' specification.

Applicants respectfully submit that cancellation of claims 1-8 without prejudice renders this rejection moot. The claims as they stand are directed to a method of inhibiting formation of amyloid deposits, removing amyloid deposits, or modulating the formation of amyloid deposits in a patient comprising administering to the patient an immunoglobulin polypeptide or fragment thereof that binds to an amyloid fibril or component or precursor thereof. All three cited

references merely teach the use of monoclonal antibodies as tools for diagnostic assays. Respectfully, the cited references do not provide guidance to the skilled artisan to formulate and use monoclonal antibodies that bind to an amyloid fibril or component or precursor thereof to inhibit formation of amyloid deposits, remove amyloid deposits, or modulate the formation of amyloid deposits in a patient. Although it may be routine to obtain humanized and chimeric antibodies as stated on pages 14-16 of the specification, the teachings of the cited references do not provide a *prima facie* case of obviousness for the claimed methods of administering antibodies to remove amyloid deposits in a patient. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 103(a).

*Sue Jones*

### **Conclusion**

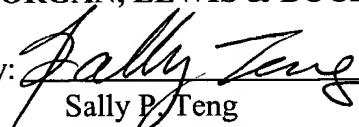
In view of the new claims and accompanying remarks, Applicants respectfully request reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there is any fee due in connection with the filing of this Amendment, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: July 18, 2001

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Paragraph beginning on line 3 and ending on line 6 of page 19 :

Samples of hybridoma cells that secrete anti- $\kappa$ 1 (57-18-H12 (ATCC Acc. No.[ \_\_\_\_ ] PTA-104)), anti- $\kappa$ 4 (11-1F4 (ATCC Acc. No. [ \_\_\_\_ ] PTA-105)) and anti-[ $\kappa$ ] $\lambda$ 8 (31-8c7 (ATCC Acc. No. [ \_\_\_\_ ] PTA-103)) monoclonal antibodies were deposited with the American Type Culture Collection (ATCC) on May 21, 1999 in compliance with the Budapest Treaty.